

PATENT COOPERATION TREATY

REC'D 24 AUG 2004

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From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT
10/552609

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/003647

International filing date (day/month/year)
06.04.2004

Priority date (day/month/year)
15.04.2003

International Patent Classification (IPC) or both national classification and IPC
B29C47/04

Applicant
DSM IP ASSETS B.V.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/003647

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/003647

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-10
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-10
Industrial applicability (IA)	Yes: Claims	1-10
	No: Claims	

2. Citations and explanations

see separate sheet

Ad V

1. Reference is made to the following documents:

- D1: US-A-5 871 802 (GAO QINGSHAN ET AL) 16 February 1999 (1999-02-16)
- D2: WO 98/18610 A (LENGERICH BERNHARD H VAN) 7 May 1998 (1998-05-07)
- D3: US-B-6 500 4631 (VAN LENGERICHS BERNHARD H) 31 December 2002 (2002-12-31)
- D4: FR-A-2 678 144 (RHONE POULENC NUTRITION ANIMAL) 31 December 1992 (1992-12-31)
- D5: DATABASE WPI Section Ch, Week 199649 Derwent Publications Ltd., London, GB; Class B04, AN 1996-493408 XP002287821 & JP 08 253423 A (TOKUSHU MENEKI KENKYUSHO KK) 1 October 1996 (1996-10-01)
- D6: US-A-4 726 948 (PERRAUDIN JEAN-PAUL ET AL) 23 February 1988 (1988-02-23)

2. None of the documents cited in the international search report discloses an extrusion process for the preparation of solid particles containing lactoferrin nor solid particles containing lactoferrin embedded in a protein-starch matrix, thus the subject-matter of claims 1-10 is considered to be novel (Article 33(2) PCT).

3. D1-D4 all refer to extrusion processes under mild conditions, to enable the use of heat sensitive components.

D1 even refers to the use of whey (see Example 1), which comprises lactoferrin. However, D1 does not specifically disclose the use of starch. Still, as D1 is considered to be a rather general teaching on the extrusion process, the use of starch, being well-known in the art of extrusion for animal feedstuffs (see also D2 and D3), is not considered to involve an inventive step (Article 33(3) PCT).

D5 and D6 disclose food products comprising lactoferrin; D5 discloses lactoferrin granules and D6 a milk substitute containing lactoferrin. When looking for another administration form of lactoferrin, the person skilled in the art would have used the teaching of D1-D4 and apply low shear/temperature extrusion as disclosed therein, without exerting any inventive skills.

Thus, the subject-matter of claims 1-10 is not considered to involve an inventive step (Article 33(3) PCT).